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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/430, 735 10/29/99 EKWURIBE

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INTELLECTUAL PROPERTY TECHNOLOGY LAW  
P O BOX 14329  
RESEARCH TRIANGLE PARK NC 27709

EXAMINER

HSU, G

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

08/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. 09/430,735	Applicant(s) Ekwurib et al.
	Examiner Grace Hsu, Ph.D.	Group Art Unit 1627

Responsive to communication(s) filed on May 10, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

70,71

Claim(s) 26-35, 46-52, and 73-97 is/are pending in the application

Of the above, claim(s) 26-35 is/are withdrawn from consideration

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 46-52 and 73-97 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### **DETAILED ACTION**

*Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is (703) 305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, Supervisory Examiner at Jyothsna.Venkat@uspto.gov or 703-308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.*

An Amendment and Response to Restriction Requirement received on May 10, 2000 was entered as Paper No. 6.

1. Claims 26-35, 46-52 and 73-97 are currently pending (claims 73-97 have been added) and claims 23-25, 53-60 and 70-72 have been canceled in the instant application.

#### *Election/Restriction*

2. Applicants election of Group II, claims 46-52, without traverse in Paper No. 6 is acknowledged. Claims 73-97 are dependent from claim 46 and are included in Group II.
3. In light of the foregoing, a species election of Group II is set forth as necessitated by applicants' amendments to the claims in the instant application.

#### *Election of Species*

4. This application contains claims directed to patentably distinct species of the claimed invention.

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5. Applicants are required in Group II to further elect from the following patentably distinct Species A-I, a single compound species that pertains to the claimed methods for each of the following:

<u>Species</u>	<u>Claim No</u>	<u>Species Type</u>
(1) A	46	amphiphilic drug- oligomer conjugate
(2) B	46	opioid
(3) C	46	oligomer
(4) D	46	lipophilic moiety/moieties
(5) E	46	hydrophilic moieties
(6) F	47	[met <sup>5</sup> ]enkephalin
(7) G	70	enkephalin
(8) H	83	cetyl-PEG <sub>2</sub> -enkephalin conjugate
(9) I	84	DHA-PEG <sub>2</sub> -enkephalin conjugate

wherein for each of the above-identified species elected, each functional and sub-functional groups, corresponding to a respective core formula and/or sub-groups therein (i.e., e.g., P<sup>1</sup>, P<sup>2</sup>, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, R<sup>5</sup>, etc.) should be defined.

Each of the species encompassed by the claimed invention represent patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 46 is generic.

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**For search purposes, applicants also should provide the chemical structure of a single compound species are defined/related to the claimed methods, wherein specific chemical formula substituents of attached to the core formula are defined either by picture or by expressing the species in terms of the variables of the formula.**

6. Applicants are required in Group II to further elect from the following patentably distinct Species J of the claimed invention:

<u>Species J</u>	<u>claim no.</u>	<u>The method of claim 46, comprising one or more lipophilic moiety:</u>
(10)	claim 48	fatty acids
(11)	claim 48	C <sub>1-26</sub> alkyls
(12)	claim 48	cholesterol

wherein for each of the above-identified species elected, each functional and sub-functional groups, corresponding to a respective core formula and/or sub-groups therein (i.e., e.g., P<sup>1</sup>, P<sup>2</sup>, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, R<sup>5</sup>, etc.) should be defined.

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 46 is generic.

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7. Applicants are required to further elect in Group II from the following patentably distinct Species K of the claimed invention:

<u>Species K</u>	<u>claim no.</u>	<u>The method of claim 46, wherein the hydrophilic moieties is selected from the group consisting of:</u>
(13)	claim 49	sugars
(14)	claim 49	PEG

wherein for each of the above-identified species elected, each functional and sub-functional groups, corresponding to a respective core formula and/or sub-groups therein (i.e., e.g., P<sup>1</sup>, P<sup>2</sup>, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, R<sup>5</sup>, etc.) should be defined.

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 46 is generic.

8. Applicants are required in Group II to further elect from the following patentably distinct Species L of the claimed invention:

<u>Species L</u>	<u>claim no.</u>	<u>The method of claim 46, wherein the one or more hydrophilic moieties comprise a sugar selected from the group consisting of</u>
(15)	claim 50	amino sugars
(16)	claim 50	non-amino sugars

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wherein for each of the above-identified species elected, each functional and sub-functional groups, corresponding to a respective core formula and/or sub-groups therein (i.e., e.g., P<sup>1</sup>, P<sup>2</sup>, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, R<sup>5</sup>, etc.) should be defined.

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 46 is generic.

9. Applicants are required to further elect in Group II, from the following patentably distinct Species M of the claimed invention:

<u>Species M</u>	<u>claim no.</u>	<u>The method of claim 46, wherein the oligomer has a formula of:</u>
(17)	claim 85	formula 1
(18)	claim 86	formula 2
(19)	claim 87	formula 3
(20)	claim 88	formula 4
(21)	claim 89	formula 5
(22)	claim 90	formula 6
(23)	claim 91	formula 7

wherein for each of the above-identified species elected, each functional and sub-functional groups, corresponding to a respective core formula and/or sub-groups therein (i.e., e.g., P<sup>1</sup>, P<sup>2</sup>, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, R<sup>5</sup>, etc.) should be defined.

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Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 46 is generic.

10. Applicants are required in Group II, to further elect from the following patentably distinct Species N of the claimed invention:

<u>Species N</u>	<u>claim no.</u>	<u>The method of claim 46, wherein the drug-oligomer conjugate has a formula or chemical structure:</u>
(24)	claim 92	as defined in claim 92
(25)	claim 93	as defined in claim 93
(26)	claim 94	as defined in claim 94
(27)	claim 95	as defined in claim 95
(28)	claim 96	as defined in claim 96
(29)	claim 97	as defined in claim 97
(30)	claim 91	as defined in claim 98

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

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Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 46 is generic.

11. Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Each of the species identified in claims above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Moreover, applicants are required in Group II to elect **a single species for each identified species group as noted above, wherein each of the functional groups of each core formula, i.e., for example R, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, R<sub>5</sub> X, Y, etc. and each respective sub-group of any of the chemical formulas defined in the corresponding claims therein should be defined.**

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

**For search purposes, applicants also should provide the chemical structure of a single compound species, wherein specific chemical formula substituents of attached to the**

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**core formula are defined either by picture or by expressing the species in terms of the variables of the formula.**

12. Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

13. Should applicants traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. These inventions are distinct for the reasons above and have acquired a separate status in the art because of their recognized divergent subject matter and/or shown by their different classifications. While some of the aforementioned groups are classified under an identical class/sub-class, the corresponding non-patent literature search remains unaffected. Each of the identified groups may require different searches. For example, methods and products groups require different searches. Therefore, restriction for examination purposes as indicated is proper.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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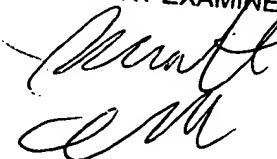
named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

*Conclusion*

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Grace C. Hsu, Ph.D., J.D. whose telephone number is (703) 308-7005. The Examiner may be reached during normal business hours, Monday through Friday from 8:30 am to 5:30 pm (EST). A message may be left on the Examiner's voice mail.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jyothsna Venkat, Ph.D., may be reached at (703) 308-2439. The fax number assigned to Group 1627 is (703) 305-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1627 receptionist whose telephone number is (703) 308-0196.

BENNETT CELSA  
PRIMARY EXAMINER



Grace C. Hsu, Ph.D., J.D.

August 14, 2000